REMARKS

Claims 90-111 are pending in the present application. Claims 1-89 have been cancelled without prejudice or disclaimer. Claims 90-111 have been newly added.

Claims 1-89 have been cancelled without prejudice or disclaimer and claims 90-111 have been newly added for the sole reason of advancing prosecution. Applicants, by cancelling any claims herein, make no admission as to the validity of any rejection made by the Examiner against any claim. Applicants reserve the right to reassert any of the claims canceled herein, in a continuing application.

New claims 90-95 and 111 are directed to a "method of generating a frozen viable cartilage." New claim 96 is directed to "[f]rozen viable cartilage." New claims 97- 106 are directed to a "method for thawing a frozen viable cartilage that was frozen in a cryopreservation–solution." New claim 107 is directed to "[t]hawed viable cartilage." Lastly, new claims 108-110 are directed to a "method of providing a patient having impaired cartilage in an organ at a target site, with a thawed viable cartilage." New claims 90-111 find support throughout the specification, examples and claims as originally filed. No new matter has been added.

New claims 90 and 97 have been written to recite "wherein upon thawing the thawed viable cartilage comprises more than 50% viable chondrocytes." Support for this recitation appears in the present specification at paragraph [0026] in the published application, US2007-0077237. No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, the USPTO asserts that the Declaration is defective for failing to identify "the city and either state or foreign country of residence of each inventor" and requires an ADS or Supplemental Declaration.

Applicant's note that both the unexecuted Declaration filed with the application on April 10, 2006 and the executed Declaration filed on July 31, 2006, correctly state both the city and foreign country of residence for each inventor. Specifically, Udi Damari resides in the city Ganiey Tikva, in the country Israel; Rivi Levi Holtzman resides in the city Rehovot, in the country Israel; and Victor Rzepakovsky resides in the city Ness Zionna, in the country Israel. Accordingly, it is submitted that the filed executed Declaration of record is ***not*** defective. If this assertion is to be maintained, express clarification is requested.

II. At page 3 of the Official Action, claims 52-89 have been rejected under 35 USC § 112, second paragraph, as being indefinite.

Claims 52-89 have been cancelled without prejudice or disclaimer. Accordingly, this rejection is moot with regard to these claims.

III. At page 6 of the Official Action, claims 52, 54-56, 68 and 72-75 have been rejected under 35 USC § 102(b) as being anticipated by Schachar et al., in light of Sigma Product Information Sheet for Dimethyl sulfoxide.

The Examiner asserts that Schachar et al. teaches each element of each of claims 52, 54-56, 68 and 72-75.

Claims 52, 54-56, 68 and 72-75 have been cancelled without prejudice or disclaimer. Accordingly, this rejection is moot with regard to these claims.

With regard to new claims 90-95 and 111 directed to a "method of generating a frozen viable cartilage," it is submitted that Schachar et al. do not teach each and every element of each of these claims as required for anticipation under 35 USC §102.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California,* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. R*ichardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond,* 15 USPQ2d 1566 (Fed. Cir. 1990).

Present claim 90 is directed to "[a] method of generating a frozen viable cartilage, comprising (a) providing a receptacle containing a viable cartilage in a cryopreservation solution at a temperature above a freezing temperature of the cryopreservation solution; (b) cooling the viable cartilage in the cryopreservation solution to a temperature below the freezing temperature of the cryopreservation solution at a cooling rate of 0.01°C/min to 3°C/min, thereby generating a frozen viable cartilage in the receptacle; and (c) transferring the receptacle to storage at a temperature equal to or below -130°C, wherein upon thawing the thawed viable cartilage comprises more than 50% viable chondrocytes". Claims 91-95 and 111 are each directly or indirectly dependent on independent claim 90.

Schachar et al. do not teach or suggest storing at a temperature equal to or below -130°C, as recited in present claim 90. In fact, Schachar et al. describe storing at a significantly higher temperature of -80°C.

Further, Schacher et al. do not teach or suggest directional cooling as presently claimed. Rather, Schachar et al. provides a method for freezing cartilage by immersing the cartilage in DMSO, cooling to -40°C at a cooling rate of -1°C/min and then storing the frozen cartilage at -80°C for as long as 4 weeks (See *Treatment groups* on page 911, right column).

Further, Schachar et al. does not teach or suggest more than 50 chondrocyte recovery (upon thawing) and concludes that cryoprotection and controlled cooling are ***required*** to increase the viability of cartilage. The cryopreservation procedure described in his study resulted in an intermediate (50%) chondrocyte recovery after thawing. "The cryopreservation protocol, however, resulted in intermediate recovery (50%) of chondrocytes and in intermediate overall graft outcome compared with fresh autografts." (*See* Abstract); and "...notwithstanding, the cryopreserved allografts still did not perform as well as the fresh autografts in many of the areas assessed." (See *Discussion* on page 918, left column).

The presently claimed subject matter provides higher post thawing viability of the frozen cartilage than the method of Schachar et al. As shown in present Table 1, the viability of the cartilage in accordance with the presently described subject matter is even more than 50% (50%, 65% or 69%, as compared to fresh cartilage). This higher viability as compared to the viability obtained by prior

cryopreservation techniques (such as that suggested by Schachar et al.) was unexpected.

In view of the foregoing, it is submitted that Schachar et al. do not teach, either expressly or inherently, each and every element of present claims 90-95 and 111, as required for anticipation under 35 USC § 102 (b).

IV. At page 8 of the Official Action, claims 52-56 and 68-75, have been rejected under 35 USC §103(a) as being unpatentable over Schachar et al. in view of Sigma Product Information Sheet for Dimethyl sulfoxide.

The Examiner asserts that Schachar et al. differ from the rejected claims with regard to how the osteochondral sample is subjected to the cooling temperatures. The Examiner further appears to assert that because "[c]hanging the temperature around a stationary sample versus physically moving the sample to environments of different temperatures produces the same effect, so long as the temperature change is at the same rate," the substitution of one method for the other to yield the predictable result of cooling the osteochondral sample at the claimed rate would be prima facie obvious to the skilled artisan.

Claims 52-56 and 68-75, have been cancelled without prejudice or disclaimer. Accordingly, this rejection is moot with regard to these claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the

design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Recently, the Federal Circuit in *Takeda Chemical Industries v. Alphapharm*, No. 06-1329, slip op. (Fed. Cir. June 28, 2007), has applied the TSM test after *KSR*. The Appellant in this declaratory judgment action argued that the claimed chemical compound was an obvious modification of a previously known compound—the modification requiring the substitution of a homolog in a different ring position. (*Id.* at 5.) The Federal Circuit rejected this, holding that "in cases involving new chemical compounds, it remains necessary to identify some reasons that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." (*Id.* at 10.) Notably, the Court also rejected the Appellant's "obvious

to try" argument, as the Appellant failed to demonstrate that one of ordinary skill would have chosen the prior art compound to modify from the millions of possibilities. (*Id.* at 15.)

With regard to new claims 90-95 and 111, it is submitted that a *prima facie* case of obviousness has not been established because whether taken alone or in combination, Schachar et al. and Sigma do not teach or suggest all the limitations of the present claims as required by *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Again, present claim 90 is directed to "[a] method of generating a frozen viable cartilage, comprising (a) providing a receptacle containing a viable cartilage in a cryopreservation solution at a temperature above a freezing temperature of the cryopreservation solution; (b) cooling the viable cartilage in the cryopreservation solution to a temperature below the freezing temperature of the cryopreservation solution at a cooling rate of 0.01°C/min to 3°C/min, thereby generating a frozen viable cartilage in the receptacle; and (c) transferring the receptacle to storage at a temperature equal to or below -130°C, wherein upon thawing the thawed viable cartilage comprises more than 50% viable chondrocytes". Claims 91-95 and 111 are each directly or indirectly dependent on independent claim 90.

Schachar et al. do not teach or suggest storing at a temperature equal to or below -130°C, as recited in present claim 90. In fact, Schachar et al. describe storing at a significantly higher temperature of -80°C.

Sigma does not cure the deficiencies of Schachar et al. because Sigma also does not teach or suggest storing at a temperature equal to or below -130°C, as recited in present claim 90.

At the onset, Applicants note that claims 90-95 and 111 are method claims and as such, the positive limitations are the active method steps. In the present case, the step claimed in claim 91, i.e., "moving the receptacle along one or more consecutive temperature gradients...," is a positive limitation. Accordingly, the Examiners assertion that "the substitution of one method for the other to yield the predictable result of cooling the osteochondral sample at the claimed rate would be prima facie obvious to the skilled artisan" is completely without merit. Schachar et al. do not teach or suggest the claimed method step of "moving...." Please *see* Example 3 in "*Claim Interpretation 'In the Examination Process'*" Technology Center 1600 Symposium, San Francisco, San Diego, Seattle, October 2005, by Brenda Brumback, Supervisory Patent Examiner Art Unit 1647, USPTO, attached hereto (Annex A). Should this rejection be maintained, the Examiner is requested to expressly address the foregoing.

Schacher et al. do not teach or suggest directional cooling and/or more the 50% chondrocyte viability (upon thawing), as presently claimed. Rather, Schachar et al. provides a method for freezing cartilage by immersing the cartilage in DMSO, cooling to -40°C at a cooling rate of -1°C/min and then storing the frozen cartilage at -80°C for as long as 4 weeks (See *Treatment groups* on page 911, right column).

Schachar et al. conclude that cryoprotection and controlled cooling are ***required*** to increase the viability of cartilage. The cryopreservation procedure described in his study resulted in 50% chondrocyte recovery after thawing (*see Abstract* and *Discussion* on page 918 left column).

Specifically, the method of Schachar et al. resulted in 50% chondrocyte recovery after thawing "The cryopreservation protocol, however, resulted in intermediate recovery (50%) of chondrocytes and in intermediate overall graft outcome compared with fresh autografts." *See* the Abstract. Schachar et al. also state that "...notwithstanding, the cryopreserved allografts still did not perform as well as the fresh autografts in many of the areas assessed." *See* page 918.

The presently claimed subject matter provides higher post thawing viability of the frozen cartilage than the method of Schachar et al. As shown in present Table 1, the viability of the cartilage in accordance with the presently described subject matter is more than 50% (50%, 65% or 69%, as compared to fresh cartilage). This higher viability as compared to the viability obtained by prior cryopreservation techniques (such as that suggested by Schachar et al.) was unexpected.

As appreciated by those versed in the art, chondrocyte viability is crucial for the longevity of grafted cartilage in order to improve the viability of post thawed cartilage after transplantation. Thus, the difference between the viability provided by Shachar et al. and that provided by the presently described subject matter is of great significance as it allows the post thawed cartilage to survive in the body and serve its desired purpose significantly longer than the post thawed cartilage provided by Schachar et al.

The high viability of the present post thawed cartilage is achieved by directional freezing of the cartilage. "Freezing can be done using any apparatus or method that will allow directional freezing of the cartilage, such as the Multi Thermal Gradient (MTG) freezing apparatus (IMT, Israel) that was used above." (*See* page 25, lines 18-20). The directional freezing also allows the long term storage at -130°C and below (for even months, *see* page 26, lines 2-3) which is not possible with storage at -80°C.

Directional freezing forces ice crystals to slowly grow into the lacunas within the ECM without causing fractures of the lacunas and as such facilitates the aforementioned long term storage and high viability of the present post thawed cartilage.

Since Schachar et al. do not perform directional freezing of the cartilage they ***cannot*** provide frozen cartilage that post thawing has a viability of more than 50% and therefore they cannot provide post thawed cartilage that is suitable for transplantation. As such, Schachar et al. alone or in combination with Sigma Product Information Sheet on DMSO cannot be regarded as suggesting the unexpected and beneficial methods of the invention.

Thus, the rejection for lack of inventive step in view of Schachar et al., in combination with Sigma, is without merit as to new claims 90-95 and 111. It is submitted that nothing in Schachar et al. or Sigma, taken alone or together, teaches or suggests the subject matter of present claims 90-95 and 111.

V. At page 8 of the Official Action, claims 52-89, have been rejected under 35 USC §103(a) as being unpatentable over Pegg et al. in view of Schachar et al.

The Examiner asserts that the combination of Pegg et al. and Schachar et al. renders the claimed subject matter obvious.

Claims 52-89, have been cancelled without prejudice or disclaimer. Accordingly, this rejection is moot with regard to these claims.

The legal authority set forth above with regard to obviousness is incorporated herein by reference in its entirety.

With regard to new claims 90-111, it is submitted that a *prima facie* case of obviousness has not been established because whether taken alone or in combination, Pegg et al. and Schachar et al. do not teach or suggest all the limitations of the present claims as required by *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

The above arguments with regard to Schachar et al. are incorporated herein by reference in their entirety.

Pegg et al. describe a method for reducing macroscopic fractures in cryopreserved arteries.

In the Official Action the Examiner asserts that it would have been obvious to one of ordinary skill in the art to apply the cryopreservation method of Pegg et al. to other types of tissue. Firstly, as also admitted in the Official Action, Pegg et al. use artery segments and not cartilage. Artery segments and cartilage are vastly different tissues that have different functions in the body, and thus, the skilled artisan would not expected them to behave the same.

Furthermore, Table 4 in Pegg et al. shows that the method disclosed therein provides, post thawing, and endothelial integrity of less than 50%, specifically, 45.8±7.3%. Thus, Pegg et al. in fact, cannot be considered as teaching a method for importing cryopreservation to a level of about 50%, as provided by the presently claimed subject matter.

Thus, the improvement in cartilage viability provided by the application and its impact on the functionality of the transplant could not have been expected in view of Schachar et al. when combined with the teaching of Pegg et al.

In view of the foregoing, it is submitted that nothing in Pegg et al. or Schachar et al., taken alone or together, teaches or suggests the subject matter of present claims 90-111.

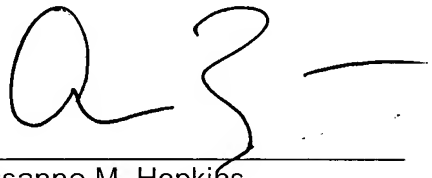
CONCLUSION

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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ANNEX A

Technology Center 1600 Symposium

San Francisco, San Diego, Seattle, October 2005

Claim Interpretation

"In the Examination Process"

Brenda Brumback
Supervisory Patent Examiner Art Unit 1647
U.S. Patent &Trademark Office
(571) 272-0961; brenda.brumback@uspto.gov

What are patent claims?

- Patent claims are the inventor's attempt to delineate by way of a single sentence in the English language the technology which applicant regards as his or her invention.

- Claim language defines property boundaries. Patent claims provide notice to the public as to the technology which is "fenced off" or protected from trespass.

Keep your eye on the claims, not on the "invention".

- Since the claims define the invention, focus must begin and remain on the claims during the examination process.

- "The invention disclosed in Hiniker's written description may be outstanding in its field, but **the name of the game is the claim.**"

  In re Hiniker Co., 47 USPQ 1523, 1529 (Fed. Cir. 1998)

Claim Interpretation

Is the careful consideration of

each and every word

in a claim to determine what the claim covers.

Ordinary and Customary Meaning

- "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a **person of ordinary skill** in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application."

Phillips v. AWH Corp., 75 USPQ2d 1321, 326 (Fed. Cir. 2005)

Ordinary and Customary Meaning

- "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation…Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the **context** of the particular **claim** in which the disputed term appears, but in the context of the **entire patent** including the specification."

Phillips, 75 USPQ2d at 1326.

Ordinary and Customary Meaning

- "Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the **claims** themselves, the remainder of the **specification**, the **prosecution** history, and **extrinsic** evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art".

- *Phillips*, 75 USPQ2d at 1327 (internal citations omitted)

Ordinary and Customary Meaning

- "Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim."

- *Phillips*, 75 USPQ2d at 1327 (internal citations omitted).

Ordinary and Customary Meaning

- The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument', consisting principally of a specification that concludes with the claims. For that reason, claims 'must be read in view of the **specification**, of which they are a part.' As we [have] stated [], the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."

- *Phillips,* 75 USPQ2d at 1327 (internal citation omitted).

Claim Interpretation MPEP 2111

Claims must be given their **broadest reasonable** interpretation consistent with the supporting description.

In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)

Claim Interpretation
MPEP 2111

A claim must be interpreted in light of the specification **without** reading limitations into the claim.

Tips

- Provide claim breadth commensurate in scope with the disclosure.
- Provide claims directed to the inventive concept.
- Avoid reach-through claims.

Red Flag Terms

- Fragments thereof
- Analogues thereof
- Derivatives thereof
  - "A compound of formula II…and its pharmaceutically acceptable salts *or derivatives* thereof."

Effect of the Preamble on Claim Scope

What is a Preamble?

A preamble is an introductory phrase of a claim. A preamble *might*:

(1) summarize the invention;

(2) summarize its relation to the prior art;

(3) summarize its intended use or properties; or

(4) constitute a limitation of the claimed device or process.

Guidance in determining when a preamble **will likely** limit a claim

1) Preambles of claims in Jepson form generally are structural or step limitations being claimed in combination with the subject matter that follows "wherein the improvement comprises".

Rowe v. Dror, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997); 37 C.F.R. 1.75(e).

2) If the preamble recites essential structure or steps or is "necessary to give life, meaning and vitality to a claim," it is likely to limit the claim.

Pitney Bowes, 51 USPQ2d at 1165-66; *Kropa v. Robie*, 88 UPSQ 478,480-481 (CCPA 1951).

Guidance in determining when a preamble is **not likely** to limit a claim

(1) When the body of the claim following the preamble is a self-contained description of the structure and does not depend on the preamble for completeness, the preamble does not usually limit the claim.

Kropa v. Robie, 88 UPSQ at 480-481; Rowe, 42 USPQ2d at 1553; and *IMS Technology Inc. v. Haas Automation Inc.,* 54 USPQ2d 1129, 1137 (Fed. Cir. 2000).

(2) A preamble that recites the use or purpose of the claimed invention generally does not limit the claim.

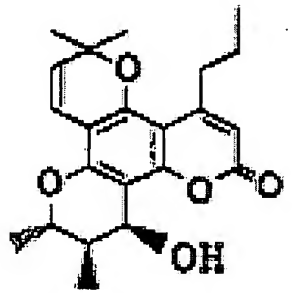
Catalina, 62 USPQ2d at 1785.

Claim Interpretation

Example 1

The Claim

1. A cancer therapeutic composition comprising a compound of structure A



and a pharmaceutically acceptable carrier.

The Prior Art

- Reference A discloses a composition comprising a compound of structure A in a pharmaceutically acceptable carrier.
- Reference A teaches that the composition is used as an antiviral therapeutic for treating human immunodeficiency virus type 1 (HIV-1) infections.

Does the prior art support a rejection?

Conclusion

- The compound and composition found in the prior art and in the instant composition are identical.
- Therefore, the prior art anticipates the claimed composition.
- The preamble of the claim merely recites an intended use of the composition and as such does not limit the claims.

- *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801,808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002)

Intended Use Limitation

- When a compound or composition is limited by a particular use, enablement of that claim should be evaluated based on that limitation. MPEP 2164.01(c)

- Prior art evaluation may or may not turn based upon an intended use. The language used and where it occurs in the claim must be considered.

See *Eaton Corp. v. Rockwell International Corp.*, 66 USPQ2d 1271 (CA FC 2003).

Claim Interpretation

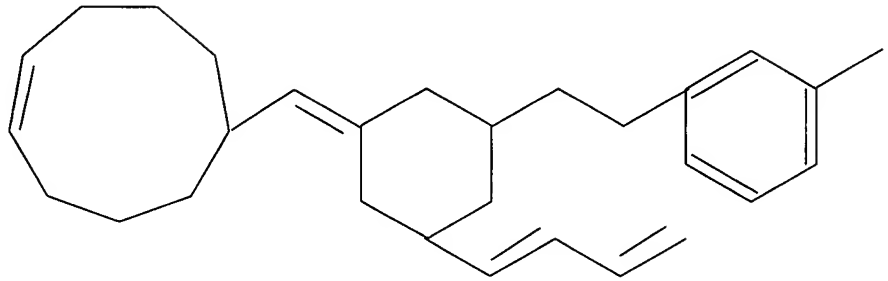
Example 2

The Claim

1. A martianase compound.

The Specification

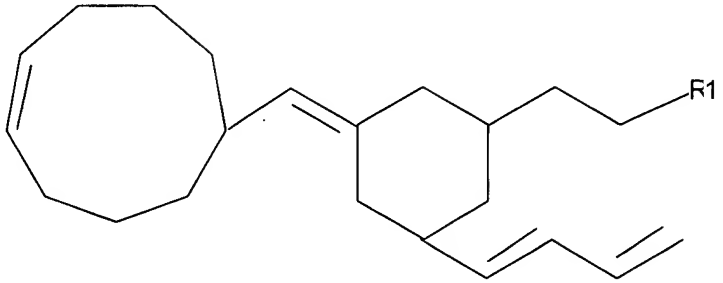
Martianase compounds are useful for the release of water from ancient Martian soil. A martianase compound is a compound having the following structure, or derivatives or metabolites thereof.



The Prior Art

(U.S. Patent No. 9,876,543)

The prior art discloses a series of compounds that are useful for treating hair loss (alopecia). The compounds of the prior art have the following structure:



wherein R1 is a substituted aryl group. The prior art patent does not disclose a specific embodiment wherein R1 is a methylphenyl group. There are, however, a number of synthetic schema disclosed and, if one were to select among the various substituents disclosed in the prior art patent, one could arrive at the same compound as that claimed in the application under examination.

Conclusion

- Therefore, U.S. Patent No. 9,876,543 would anticipate the invention of claim 1.

- When writing this rejection, the examiner should explain how the term ‘martianase’ is being used.

Claim Interpretation

Example 3

Sample Claim

1. A method of ***enhancing corneal healing*** comprising:

    administering to the eye a composition comprising vitamin A and a sterile buffer.

Sample Prior Art

- Reference A discloses a solution of vitamin A and sterile buffer in the form of eye drops.

- Reference A teaches the use of the eyedrops to rewet contact lenses.

Does the Prior Art Support a Rejection?

- Compare the compositions used
- Compare the active steps of the method

Conclusion

- The prior art composition and the instantly claimed invention are identical, as are the methods of administration.
- There is no difference between the patient populations in the instant method and the prior art method.
- Therefore, the application of the prior art-taught eye drops would inherently result in the enhancement of any corneal healing.

Consideration of Intended Use Limitations for Purposes of Applying Prior Art

If the prior art fails to discuss the intended use and the examiner has a basis for asserting that prior art product is capable of performing in the claimed manner, the claims should be rejected.

"(T)he recitation of a new intended use for an old product does not make a claim to that old product patentable."

In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

In the rejection, the examiner should set forth the basis for stating that the prior art is capable of performing the intended use.

Claim Interpretation

Example 4

The Claim

1. A vaccine comprising an isolated protein comprising SEQ ID NO:1 or a portion thereof which is antigenic.

Vaccine

Dorland's Medical Dictionary (25th ed. 1974)

– a suspension of attenuated or killed microorganisms administered for the prevention, amelioration, or treatment of infectious diseases

Patentability Determination- Vaccine

Prior Art

- A reference which discloses the composition comprising the recited protein in a pharmaceutically acceptable carrier would anticipate the claimed invention.
- Composition comprising a deleterious substance (sodium azide) would not usually be considered a vaccine

Claim Interpretation

Product-by-Process Claims

What is a Product-by-Process Claim?

A product-by-process claim is a **product** claim.

A product-by-process claim is one in which a product is defined at least in part in terms of the **method or process** by which it is made.

Product-by-Process Claims MPEP 2113

- Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.
- Once a product appearing to be substantially identical is found and a 35 U.S.C. 102 /103 rejection made, the burden shifts to the applicant to show an unobvious difference.
- The use of 35 U.S.C. 102 /103 rejections for product-by-process claims has been approved by the courts.

Examining Product-by-Process Language (cont'd)

How can the examiner examine the claim if the claimed structure is unknown?

If the claimed product appears to be the same or similar to that of the prior art, the claim should be rejected under 102/103.

Advise the applicant that the claim is being construed as a product-by-process claim.

See MPEP 2113.

Examining Product-by-Process Language (cont'd)

Once the examiner provides a **rationale** which supports the conclusion that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the **burden shifts** to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product.

In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

A statement or argument by the attorney is not factual evidence. MPEP 716.01

Claim Interpretation

Example 5

The Claims

1. An isolated and purified polynucleotide that encodes a protein that binds a black hole growth factor.

2. The polynucleotide of claim 1 comprising SEQ ID NO: 1.

The Specification

- The specification discloses the isolation of a black hole **protein** (BHP) from big bang cell line Explodin1 using a subtraction hybridization methodology. This protein was used to generate **antibodies** against BHP and these antibodies were used in expression cloning experiments to isolate a **cDNA** molecule (SEQ ID NO: 1) from the Explodin1 cell line that encodes BHP.

The Specification (cont.)

- The specification also discloses results from a Southern blot using Explodin1 DNA that reveals that this cell line has a **single** Explodin1 allele. The Southern blot also shows a **single** 1700 base pair *Eco*R1 genomic DNA fragment that hybridizes with SEQ ID NO: 1. Results of Northern blot experiments reveal a **single** band when SEQ ID NO: 1 is used as a probe.

The Specification (cont.)

- BHP is a **207 kd** protein and has **seven** transmembrane domains. Gene mapping experiments indicate that the BHP gene is present on chromosome 7 at position p4 (**7p4**).

Prior Art
(Hawkings et al.)

- Hawkings *et al.* disclose the isolation of a nucleic acid from the Explodin1 cell line. This nucleic acid encodes a **207 kd** protein having **seven** transmembrane domains.

- This protein includes a catalytic domain that is homologous to other cation channels and, when activated using heat, results in the massive expansion of cell size due to an increase in water uptake by a cell. Southern blot experiments reveal that this protein is encoded by a DNA sequence present on a 1700 base pair *Eco*R1 genomic DNA fragment and gene mapping experiments indicate that this fragment of genomic DNA is present on chromosome 7 at position p4 (**7p4**).

- Hawkings *et al.* disclose the isolation of a cDNA molecule that encodes the 207kd protein described, but do **not** present any sequence information.

Rejection

- Claims 1 and 2 are rejected under 35 USC 102(x) as being anticipated by Hawkings *et al.*
  - The instantly claimed invention is drawn to a polynucleotide that encodes a protein that binds to the black hole growth factor (BHGF). Claim 2 recites that this polynucleotide has the sequence set forth in SEQ ID NO: 1.
  - Hawkings *et al.* disclose the isolation of a cDNA molecule that appears to be identical to that instantly claimed. In particular, they disclose the isolation of a cDNA molecule that maps to chromosome **7p4** and encodes a **207kd** protein.
  - It is noted that Hawkings *et al.* do not disclose the sequence of the cDNA or protein or its ability to encode a protein that binds BHGF. However, because their cDNA was obtained from the **same cell line**, has the **same genomic DNA Southern blot** pattern, and maps to the **same genomic locus**, it appears to be the same polynucleotide as that instantly claimed.

Prosecution Issues

1. Applicant may provide a showing that the cDNA of Hawkings *et al*. does not encode a protein that binds BHGF.

2. Applicant may provide a showing that indicates that the cDNA of Hawkings *et al*. has a sequence other than SEQ ID NO: 1.

   This showing might overcome a rejection of claim 2, but would not necessarily overcome a rejection of claim 1 in the absence of the showing in (1) above.

Technology Center 1600 Symposium

San Francisco, San Diego, Seattle, October 2005

Thank you for attending!

Claim Interpretation

"In the Examination Process"

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